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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------|-------------|----------------------|-------------------------|------------------|
| 09/945,250 | 08/31/2001 | Charles G. Irvin | 2879-84 | 1940 |
| 22442 | 7590 | 10/03/2003 | EXAMINER | |
| SHERIDAN ROSS PC | | | HADDAD, MAHER M | |
| 1560 BROADWAY | | | ART UNIT | PAPER NUMBER |
| SUITE 1200 | | | 1644 | |
| DENVER, CO 80202 | | | DATE MAILED: 10/03/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/945,250 | IRVIN, CHARLES G. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-3 and 15-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is an antibody, classified in Class 424, subclass 158.1.
- II. Claims 1, 4-5 and 15-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is an antisense oligonucleotide, classified in Class 514, subclass 44.
- III. Claims 1, 6 and 15-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β -specific ribozyme, classified in Class 515, subclass 44.
- IV. Claims 1, 7 and 15-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β receptor agonist, classified in Class 514, subclass 1.
- V. Claims 1, 8 and 15-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β receptor antagonist, classified in Class 514, subclass 1.
- VI. Claims 1, 9 and 10-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β protein, classified in Class 424, subclass 184.1.
- VII. Claims 1 and 10-30, drawn to a method to protect a mammal from airway hyperresponsiveness and/or airflow limitation associated with a respiratory disease involving an inflammatory response with a TGF β -regulating agent, wherein the TGF β -regulating agent is an isolated nucleic acid molecule encoding TGF β 1, classified in Class 514, subclass 44.
- VIII. Claims 31-34, drawn to a method for prescribing treatment for airway hyperresponsiveness and/or airflow limitation with a respiratory disease involving an

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inflammatory response with a TGF β -regulating agent, classified in Class 424, subclass 9.1.

- IX. Claims 35-39, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β protein, classified in Class 530, subclass 351.
- X. Claims 35 and 40-44, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is an isolated nucleic acid molecule encoding a TGF β protein, classified in Class 536, subclass 23.5.
- XI. Claims 35 and 45, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is an antibody, classified in Class 530, subclass 388.23.
- XII. Claims 35 and 46, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is an antisense oligonucleotide, classified in Class 536, subclass 24.1.
- XIII. Claims 35 and 47, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β -specific ribozyme, classified in Class 536, subclass 24.5.
- XIV. Claims 35 and 48, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β receptor agonist, classified in Class 514, subclass 1.
- XV. Claims 35 and 49, drawn to a formulation comprising a TGF β -regulating agent, wherein the TGF β -regulating agent is a TGF β receptor antagonist, classified in Class 514, subclass 1.

2. Groups IX-XI are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, ribozyme, agonist and antagonist differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups 1-VIII are different methods. A method to protect a mammal from airway and a method for prescribing treatment for airway differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups IX-XI and 1-VIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group XI can be used for affinity purification, in addition to the recited methods. The nucleic acids of Group X can be used for Northern blot hybridization, in addition to the recited methods. The protein of Group IX can be used to make antibodies, in addition to the recited methods. The ribozymes of Group XIII can be used to ribozyme to destroy endogenous messages and inhibit translation, in addition to the recited methods.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.


6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
October 1, 2003


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

10/1/03